PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
A61B 17/115, A61F 2/06, A61B 17/064

A1

(11) International Publication Number: **WO 97/03616**

(43) International Publication Date: 6 February 1997 (06.02.97)

(21) International Application Number: PCT/GR96/00017

(22) International Filing Date: 5 July 1996 (05.07.96)

(30) Priority Data:
950100267 14 July 1995 (14.07.95) GR

(71)(72) Applicants and Inventors: SKARDOUTSOS, Spiros [GR/GR]; 16 K. Kotta, N. Psychico, GR-155 25 Athens (GR). CONSTANTINOU, Marios [GR/GR]; 9 Thrakis, Kifissia, GR-145 61 Athens (GR).

(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: ANGIOSURGICAL DEVICE AND VASCULAR GRAFT AND VASCULAR ANNULUS FOR VESSEL-VASCULAR GRAFT BINDING

(57) Abstract

This invention aims at the trapping of the vessel free cut end by plug-button connectors and its binding with the vascular graft. According to the invention a stapler whose mandibles are perimetrically closed towards a shaft of the device which has the vascular graft, is equipped with plug-button connectors and can place them stapling the vessel-vascular graft. It can also only have part of the ligaments (plug or button) and the corresponding one can be integrated at the vascular graft or may have the graft which forms free double ends at its edge and all their mechanisms are integrated. Alternatively, the vascular graft with the free double ends can be bound to the vessel without the help of the device. Finally, and intermediate binding annulus can be employed between vessel-vascular graft, which is bound to the vessel by plug-button connectors in the same way as the graft.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

ANGIOSURGICAL DEVICE AND VASCULAR GRAFT AND VASCULAR ANNULUS FOR VESSEL-VASCULAR GRAFT BINDING

This invention refers to the safe and blood-proof connection of a vessel with a vascular graft either by an automatic device or by hand.

The anastomosis of a vessel to a vascular graft is problematic by nature due to the pathological and brittle state of the vessel wall in cases where part of the vessel must be replaced by a vascular graft e.g. aortic aneurysm and due to the presence of hydraulic pressures and pulse leading to sporadic ruptures of the wall by the stapler clip itself e.g. stitch employed for the anastomosis.

The anastomosis of vessel - vascular graft must be blood-proof otherwise the patient's life is in great danger.

The application of such an anastomosis requires the interruption of the blood flow through the vessel which is accomplished by the placement of a vascular clamp. The duration of the interruption of the blood flow is a major factor for the outcome of the operation and must be the least possible one considering the numerous side effects which it causes to the organism.

The currently, extensively applied suturing means exerts great pressure against the vessel wall at the binding point due to its small diameter, resulting in ruptures of this wall, to a smaller or larger extent, frequently leading to uncontrolled haemorrhage.

The present invention aims at the safe and blood-proof vessel-vascular graft binding eliminating increased tensions from the stapler clip to the vessel wall and consequently at the preservation of its integrity as well as the execution of this binding in less time. The

above mentioned are accomplished by the use of plug-button ligaments. The invention reveals the alternative ways of their use either by an automatic stapler equipped with such ligaments or by a vascular graft where the plug or the button or both parts of the ligaments are integrated or finally by the application of an annulus first to the vessel by plug-buttons ligaments and then to the vascular graft by a simple mechanic binding.

The short description of the following figures refers to the realisation of the invention given as an example without the intention of limiting it.

Figure 1: Is the representation of the angiosurgical device.

Figure 2: Is the representation of the attachment of the device, the shaft.

Figure 3: Is the representation of the shaft coated by a vascular graft.

Figure 4: Is the representation of a plug-button connector.

Figure 5: Is the representation of the angiosurgical device equipped with plug-button connectors.

Figure 6: Is the representation in cross-section of the angiosurgical device bringing the vascular graft to the suturing point.

Figure 7: Is the representation of a vascular graft with free double ends at the edge.

Figure 8: Is the representation of a vascular graft with free double ends and integrated plug - button connectors.

Figure 9: Is the representation of the suturing of a vessel-vascular graft by plug-button connectors.

During the referred suturing procedure, the vessel wall is maintained in contact with the wall of the vascular graft by

compression among the bases of a much larger surface than the transverse surface of the axis which penetrates the vessel wall.

The attachment is accomplished as the axis of the connector penetrates the vessel and possibly the graft - unless the connectors are integrated in the graft as it is safely "locked" at the button receptor.

The small differences in thickness of the vessel wall are covered either by the fact that, occasionally, the axis enters the button receptor at different depths or in the case of the integrated button in the vascular graft by the fact that the axis can enter the thickness of the graft wall.

The placement and connection of the graft or the ring to the vessel can be employed either by the use of the described device or by hand as long as the connectors are integrated in them, either by clamp placed by each of the plug - button connectors.

Referring to the invention in detail in figure (1) we can see an angiosurgical device which has an attachment at the shaft (11) and mobile mandibles which enclose the shaft and converge towards it during the suturing. The sutured elements are placed in between shaft-mandibles and pressed between the largest perimeter of the shaft and the corresponding points of the inner surface of the mandibles next to their edges (23).

The shaft is bound to the main body of the device with a receptor (13), from which it can be detached, while the mandibles are bound to the main body by the articulations (22).

Figure 2 shows a shaft which has a smooth free edge and its larger perimeter is next to this edge. The free edge of rounded or oval cross-section enters the vessel lumen as far as the largest

perimeter.

Figure 3 shows a shaft coated by a vascular graft whose edge exactly covers the largest perimeter of the shaft (12). The vascular graft enters the vessel lumen together with the edge of the shaft. The vessel and vascular graft are compressed in between the shaft and mandibles when the device is used.

Figure 4 shows a plug-button connector. The thin axis (42) penetrates the vessel wall and enters the button receptor (44) where it locks. The vessel wall is trapped among the wide bases of the plugs (41) and the buttons (43).

Figure 5 shows the angiosurgical device equipped with plug-button connectors. The buttons (43), are at the largest perimeter of the shaft, in receptors, and the plugs (41) are at the corresponding points of the mandibles (23) in such a way so that during the convergence of the mandibles towards the shaft and the pressure on it each plug is bound with the corresponding button.

Figure 6 shows the shaft (11), in cross-section at the suturing level, which has buttons (43) coated by graft (71) and around it the mandibles (21) which have the plugs (41). The buttons are uniformly distributed in the perimeter of the shaft.

Figure 7 shows a vascular graft (71) which by adhesion, has parts made of its own material or of another bio-compatible material (72) which surround this edge of the graft and form free double ends.

Figure 6 shows a vascular graft (71) with free double ends at its edge, which has integrated plug-button ligaments, the buttons (43) are at the edge of the outer surface of the graft tube, the plugs (41) are at the end of the inner part of the adhesive parts (72). The binding with the vessel is executed by trapping the edge of the

vessel between the cut ends of the graft connected to the plug-buttons connectors.

Figure 9 shows the binding of a vessel to a vascular graft executed by the binding of each plug with the corresponding button.

Figure 10 shows a vascular annulus (81) consisting of an integral tube that forms at its one edge free double ends, its inner cut end is formed by the edge of the tube (84) and the outer by the part or the parts which can converge and cover the outer surface of the inner cut end.

At the edge of the outer surface of the inner cut end (84) are the buttons of the plug-button connectors and at the corresponding points of the inner surface of the outer cut end (83) are the plugs, in such a way that with the convergence of the two cut ends, the plug is bound to the corresponding button trapping the intermediately placed edge of the vessel.

The other edge of the annulus (82) has a receptor for simple mechanic binding to the edge of the graft which has the corresponding receptor.

Figure 11 shows a vascular annulus (81) integrated at the edge of the vascular graft (71) in a way that the vascular graft coats the whole inner surface of the ring. The annulus forms free double ends (41, 43) as described in figure 9, in a way that the trapping of the vessel (60) between the cut ends of the annulus can create integral continuity of the vessel-vascular graft contact.

CLAIMS

1. The angiosurgical device is characterised by the fact that it is used for the binding of a vessel - vascular graft. This device has an oblong attachment, of unequal thickness, the shaft (11) is connected to the main body of the device and it can be covered by a vascular graft or a vascular ring. The device has mobile mandibles (21) joined to the main body of the device by articulations (22). The mandibles are perimetrically placed around the shaft, in a distance from the shaft, before the suturing. The device has a mechanism for the convergence of the mandibles and their approach towards the shaft during the suturing.

2. The angiosurgical device according to the first claim above, is characterised by the fact that the upper shaft (11) is connected, by one edge (13), to the main body of the device from which it can be detached by exerting controlled pressure on the shaft and can be placed on it again.

3. The angiosurgical device according to the 1st & 2nd claims above, is characterised by the fact that the free end of the shaft is made smooth, with a rounded or oval cross-section and next to this edge the largest perimeter of the shaft (12) is formed, where the edge of the graft or the annulus is placed. This perimeter, together with the edge of the graft or the annulus, enters the vessel lumen during the suturing procedure.

4. The angiosurgical device according to the above claim, is characterised by the fact that the shaft has receptors at the point of its largest perimeter (12). The buttons or the plugs of the plug-button connectors are placed perimetrically to these receptors.

5. The angiosurgical device according to the 1st claim above, is

characterised by the fact that the mobile mandibles (21) form a curved surface with the concave part towards the shaft, and is also characterised by the fact that the points of the inner side of the mandibles next to their free edge (23) correspond to the points of the largest perimeter of the shaft towards which they converge and form the perimeter (12) during suturing.

6. The angiosurgical device according to the 5th claim above, is characterised by the fact that receptors exist, next to the free edges of the mandibles (23) and at their inner side. The plugs or buttons of the connectors that correspond to the ones on the shaft are attached on these receptors.

7. The angiosurgical device according to the above claim, is characterised by the fact that during the suturing, the sutured elements, that is, the edge of the vessel and the edge of the graft are pressed together in between the corresponding points of the shaft (12) and the mandibles (23).

8. This angiosurgical device according to the 7th claim above, is characterised by the fact that during the compression of the sutured elements between shaft-mandibles, each plug is bound to the corresponding button making the vessel - vascular binding permanent (figure 9).

9. The vascular graft according to the 1st claim is characterised by the fact that next to one of its edges it has an attached part as of the graft or of another bio-compatible material (72). The parts encircle the corresponding part of the graft in a way that when these parts converge at the graft, their edges form the perimeter of the edge of the graft so that free double ends are formed at the edge, i.e. the inner cut edge from the integral tube of the vessel and the outer

cut edge from the attached parts. The free edge of the vessel is trapped in between the two cut ends during the suturing.

10. The vascular graft according to the 9th claim is characterised by the fact that the integrated buttons or plugs of the plug-button connectors are on the inner surface of the outer cut end of the edge of the graft. And, the corresponding buttons or plugs are on the outer surface of the inner cut end, at corresponding points. During the suturing, each plug is bound to the corresponding button, permanently trapping the edge of the vessel between the two cut ends of the graft.

11. The vascular graft according to the 10th claim, is characterised by the fact that it is on the angiosurgical device as described in the 1st requirement above. The main tube of the graft (72) is in contact with the inner surface of the mandibles (21) from which during the suturing they are pushed and pressed in a way that each plug is bound to the corresponding button, permanently trapping the edge of the vessel which was placed in-between the shaft and mandibles.

12. The vascular annulus according to 1st claim above, is characterised by the fact that it can be the intermediate ligament between the vessel and vascular graft. This vascular annulus consists of bio-compatible elastic material and forms at its one edge free double ends, the inner cut end constitutes part of an integral tube (84) and has the buttons or the plugs of the plug-button ligaments at the edge of its outer surface. The outer cut end (83) has at the edge of its inner surface the corresponding plugs or buttons at corresponding points in a way that during the convergence of the two cut ends, each plug is bound to the corresponding button trapping the edge of the vessel which has been placed in-between.

13. The vascular annulus according to the 12th claim above, is characterised by the fact that the edge which does not form free double ends has a receptor for simple mechanic binding to the edge of the graft (82).

14. The vascular annulus according to the 12th claim above, is characterised by the fact that is integrated at the edge of the vascular graft (Fig. 11) in a way that this edge of the graft covers the inner surface of the tube formed by the vascular annulus.

15. The vascular annulus according to the 12th claim, is characterised by the fact that has an angiosurgical device as described by the 1st claim covering part of the shaft as far as its largest perimeter. The outer cut end is pressed by the mandibles to bind itself to the inner cut end of the annulus with the plug-button connectors, trapping the free cut end of the vessel which has been placed in between.

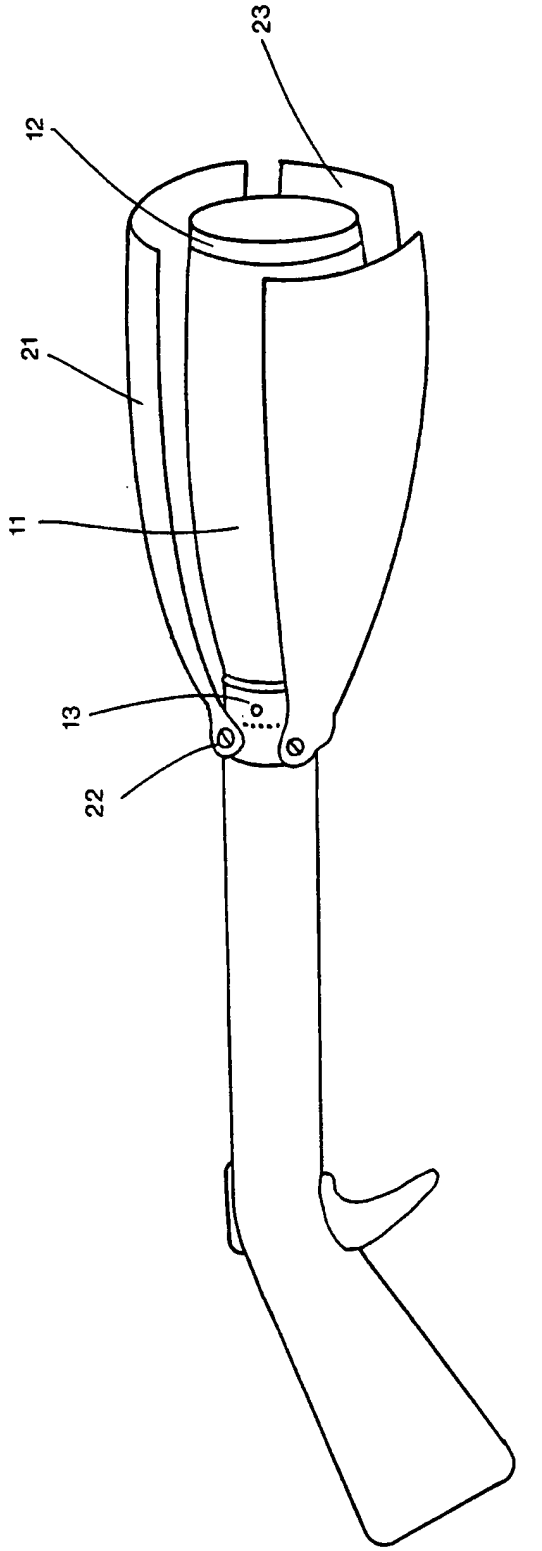

Fig. 1

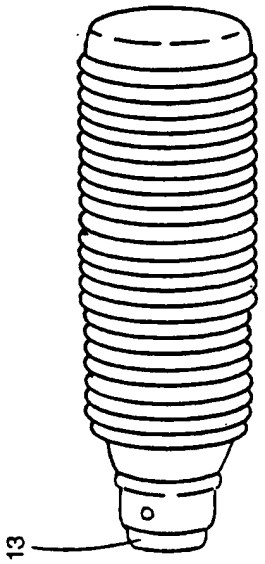

Fig. 3

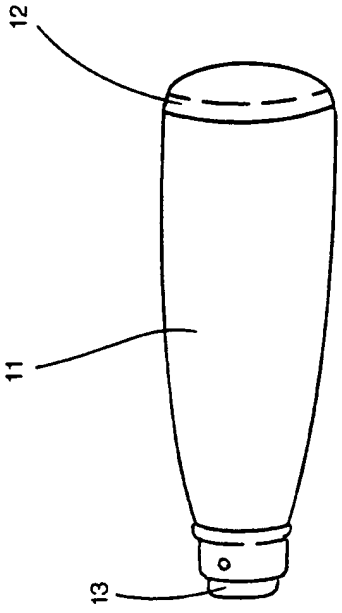

Fig. 2

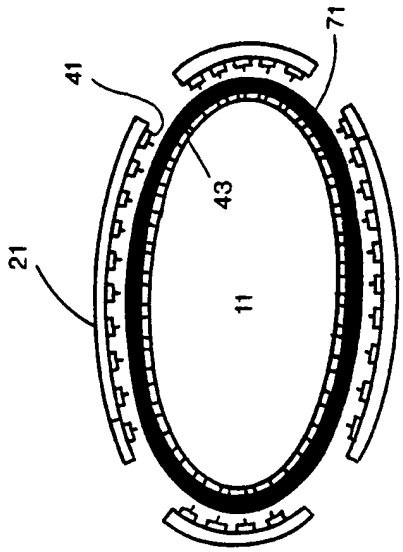

Fig. 6

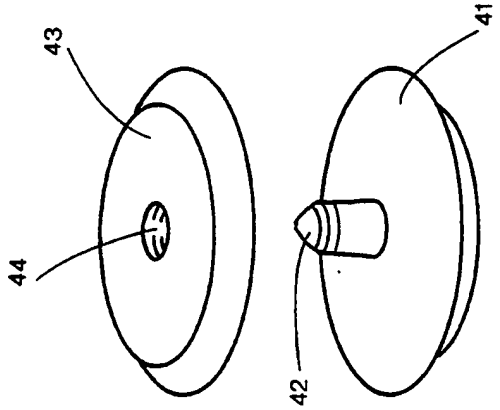

Fig. 4

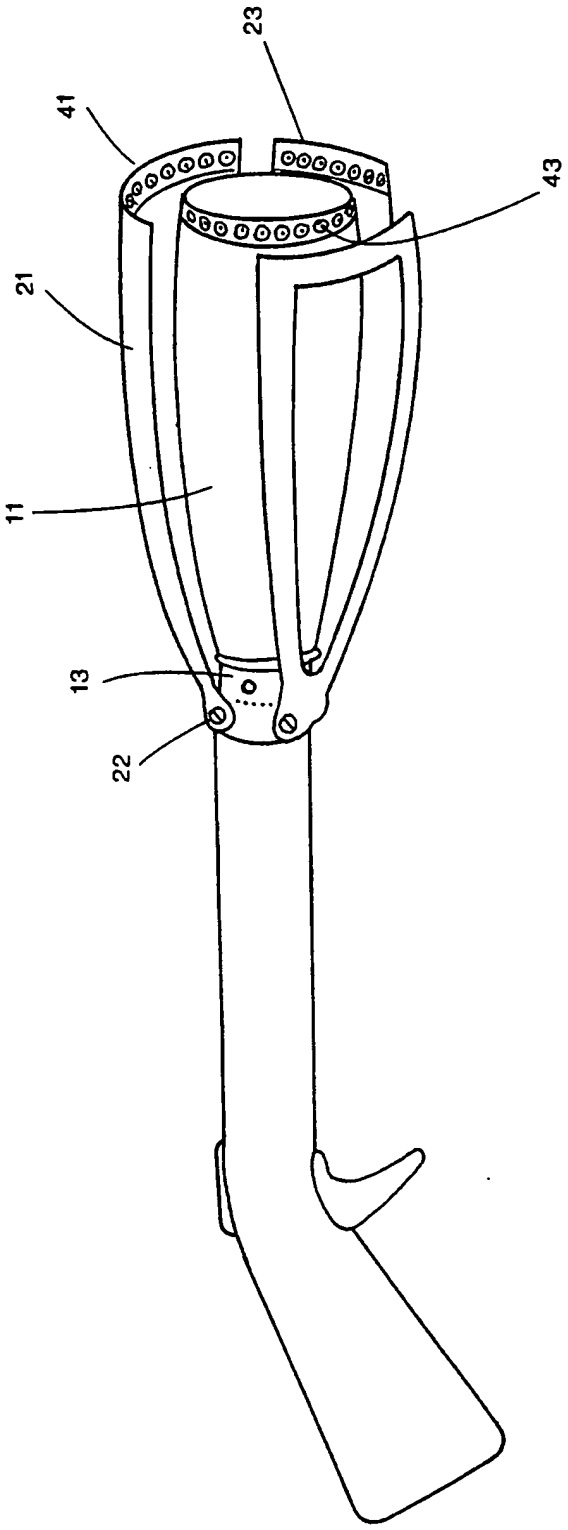

Fig. 5

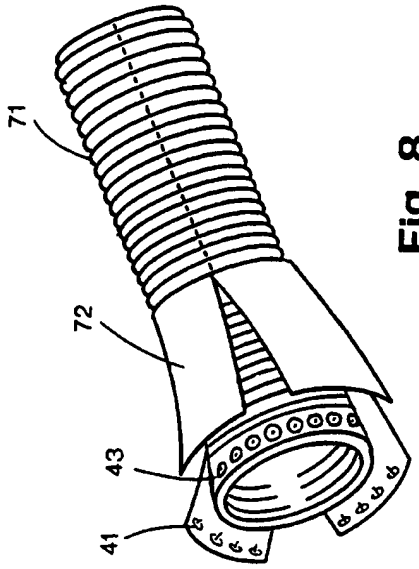

Fig. 8

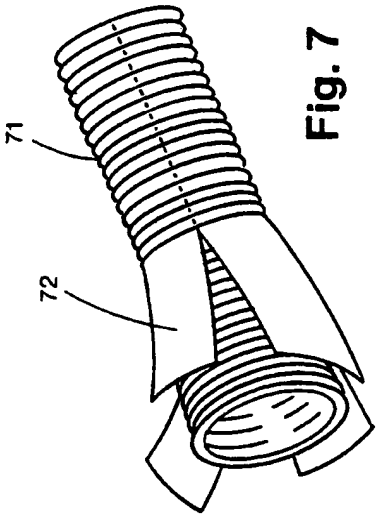

Fig. 7

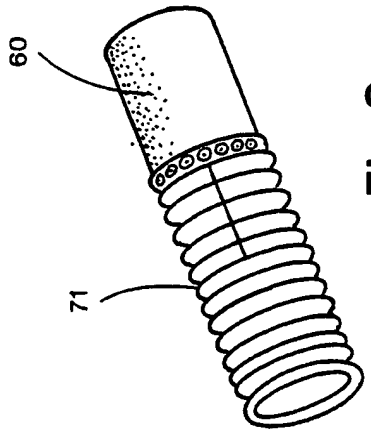

Fig. 9

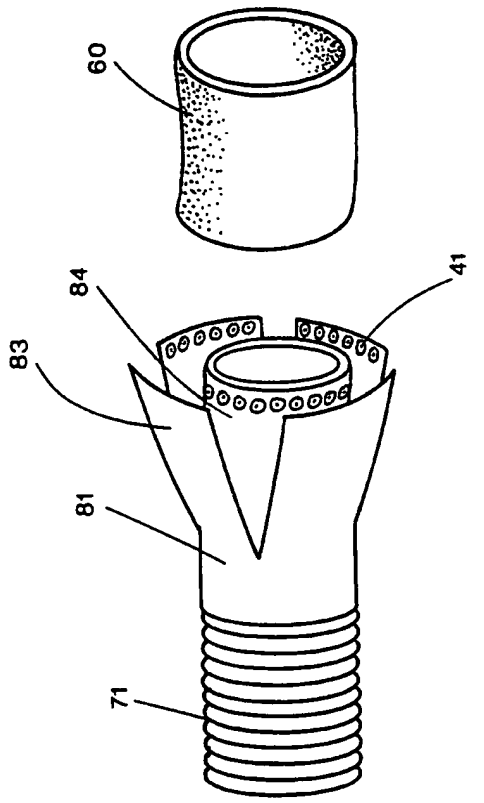

Fig. 11

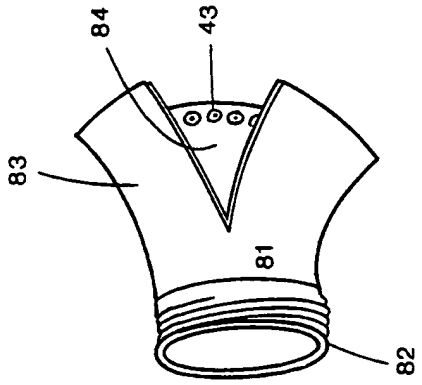

Fig. 10

INTERNATIONAL SEARCH REPORT

Inte. nal Application No
PCT/GR 96/00017

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/115 A61F2/06 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 151 105 (KWAN-GETT CLIFFORD) 29 September 1992 see column 8, line 9 - line 47 ---	1
A	US,A,4 352 358 (ANGELCHIK JEAN P) 5 October 1982 see column 4, line 15 - line 22 ---	9,12
A	WO,A,93 00868 (OWEN EARL RONALD) 21 January 1993 see page 1, line 27 - page 2, line 18 -----	9

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
3 October 1996	14. 10. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Gérard, B

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter al Application No
PCT/GR 96/00017

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5151105	29-09-92	NONE		
US-A-4352358	05-10-82	NONE		
WO-A-9300868	21-01-93	AU-B-	658915	04-05-95
		CA-A-	2112474	21-01-93
		EP-A-	0593600	27-04-94
		JP-T-	7500023	05-01-95
		US-A-	5456714	10-10-95